

Warsaw, 16/10/2018

## REQUEST FOR PROPOSALAS No 60/2018 – SARCO

### I. ORDERING PARTY:

<b>OncoArendi Therapeutics SA</b>  Zwirki i Wigury 101 02-089 Warszawa VAT ID 728 27 89 248	<b>Contact person</b>  Joanna Lipner <a href="mailto:j.lipner@oncoarendi.com">j.lipner@oncoarendi.com</a> phone no. +48 512 974 496
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### II. OBJECT OF THE REQUEST / PROPOSAL:

#### **Expert consulting service related to preclinical safety assessment program for OATD-01 drug candidate, related to developmental and reproductive toxicity (DART) studies**

The order carried out as a part of the projects titled:

SARCO: PRECLINICAL AND CLINICAL DEVELOPMENT OF SMALL MOLECULE OATD-01, A DRUG CANDIDATE FOR THE TREATMENT OF SARCOIDOSIS,

which would be co-financed by the National and European Union Funds through the sectoral programme InnoNeuroPharm (Call for proposals 3/1.2/2018) and because of the competitiveness principle.

### III. THE FORM OF THE ORDER:

- III.1 The Request is not made under the The Public Procurement Law (29/01/2004 i.e. Dz. U. z 2013 r., poz. 907 z późn. zm.).
- III.2 This order is carried out in accordance with the principle of competitiveness, openness, transparency and equal access.
- III.3 The Ordering Party reserves the right to cancel this procedure without providing reasons, and also to complete the procedure without choosing the winning tender.
- III.4 In the course of examination and evaluation of the offers the Ordering Party may require Contractors to present explanations concerning the content of submitted bids.
- III.5 The Ordering Party reserves the right to change the content of this request. If the changes can affect the content of tenders submitted in the procedure, the Ordering Party shall extend the tender submission deadline. Any changes made shall be provided promptly to all tenderers to which the request was sent and shall be binding on them.
- III.6 This procedure does not set the obligation for OncoArendi Therapeutics SA to sign any formal contracts.
- III.7 It is not possible to make an offer for a part of an order.

### IV. CONDITIONS FOR PARTICIPATION IN THE PROCEEDINGS:

- IV.1 The Request for offers relates to potential Contractors whose scope of business activity is in full compliance with the subject of this Request.
- IV.2 The offers may be issued by parties who:
  - A. have the necessary qualifications and necessary human resources for executing the contract,
  - B. have at least 5 years of experience in providing consulting service related to preclinical drug development programs,
  - C. within the last 3 years designed and oversaw for third parties at least 10 development programs from early to late stage, including FiH enabling preclinical safety programs for new molecular entities,



- D. within the last 3 years designed and oversaw for third parties at least 10 programs to study toxicology on reproduction,
- E. within the last 3 years performed at least 10 audits of CRO's research sites conducting preclinical GLP studies,
- F. within the last 3 years prepared for third parties at least 10 Investigator's Brochures,
- G. are in a good economic and financial standing, which assures proper execution of the project,
- H. will pursue the contract in a way that is beneficial to the environment by minimizing the consumption of materials, raw materials, energy, etc. (with environmental certificates such as ISO).

As a proof of the above, the Ordering Party requires that the Contractor submit, along with the tender, a statement about fulfilling conditions for participation in the proceedings. The model statement is attached as Appendix 2 to this request for proposal.

IV.4 Regarding human resources, the Ordering Party requires the Service Provider to engage experts with documented experience in:

- A. designing non-clinical drug development strategies in the context of full development program,
- B. designing ICH, EMA & FDA compliant, developmental and reproductive toxicity [DART] studies for innovative medicinal products for human use; [ICH (*International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use*), EMA (*European Medicines Agency*), FDA (*Food and Drug Administration*)]
- C. preparing and verifying DART study protocols and reports,
- D. interpretation and evaluation of DART study results,
- E. interpretation and evaluation of pathology slides,
- F. study monitoring,
- G. preparing Investigator's Brochure,
- H. regulatory support and interaction with health authorities,

As a proof of the above, the Ordering Party requires that the Contractor submit, along with the tender, a statement about fulfilling conditions for participation in the proceedings (the model statement is attached as Appendix No. 2 to this request for proposal) and CV's of the above mentioned experts.

IV.5 Excluded from the proceedings shall be those contractors who are personally or equity related to the Ordering Part by in particular:

- A. participation in the company, in a civil or limited partnership.
- B. holding at least 10 % shares or interests.
- C. serving a function of a member of the supervisory organ, a member of the management organ or proxy.
- D. having family ties, such as by marriage, by lineage at first or second degree, by adoption, guardianship or custody.

As a proof of the above, the Ordering Party requires that the Contractor submit, along with the tender, a statement about not being related to the Ordering Party. The model statement is attached as Appendix 3 to this request for proposal.

IV.4 Issuing the offer represent the full acceptance of the rules set in this Request.

## **V. DETAILED DESCRIPTION OF THE OBJECT OF THE REQUEST:**

CPV code: 73200000-4

The subject of the order is a consulting service and expert advice on pre-clinical safety assessment program for the drug candidate OATD-01 referring to developmental and reproductive toxicity (DART) studies.

Scope of the order:

- designing the DART studies' program,
- designing protocols for individual DART studies',
- interpretation and evaluation of studies' results,
- interpretation and evaluation of histopathology slides,
- verification of DART study reports,
- verification of Investigator's Brochure,
- monitoring of studies performed by CRO,
- performing an audit of CRO's research site,

The ordering party anticipates the demand for expert consulting services in the amount of approx. 2000 hours.

The Ordering Party reserves the right not to use the full estimated number of hours indicated above.

The expert is not entitled to apply to the Ordering Party with claims for the use of the full estimated number of hours and will receive remuneration only for hours ordered.

Contract period: from signing the contract until 30/06/2020.

## VI. EVALUATION OF THE OFFERS:

### VI.1 Price – weight: 90% (90 pts.)

In this criterion point will be calculated according to the formula below:

Points received  $P_c = C_{\min} / C_{\text{evaluated}} \times 90$  pts.

where:

$P_c$  – Points received

$C_{\min}$  – the smallest Net price

$C_{\text{evaluated}}$  – Net price of the offer being evaluated

90– weight of the criterion (90%)

### VI.2 Payment deadline – weight: 10% (10 pts.)

In the payment deadline, points will be awarded according to the formula:

10 points - when the payment deadline is 60 or more days from the invoice delivery

5 points - when the payment deadline is between 30 and 59 days from the invoice delivery

0 points - when the payment deadline is less than 30 days from the invoice delivery

VI.3 In the case of two or more tenders with equal number of points awarded, to guarantee performance of the contract in a manner favorable to the environment, by providing minimize the consumption of materials, raw materials, energy, etc. any environmental certifications will be taken into consideration (eg.ISO).

If the abovementioned does not allow to choose the best offer, the Ordering Party shall call Contractors who submitted equally evaluated offers to submit, within the period specified, additional offers. Contractors cannot offer higher prices than those offered in the tenders.

## VII. HOW TO PREPARE AND SUBMIT THE OFFER:

VII.1 The offer should be signed by the person authorized to represent the institution.

VII.2 Each contractor may submit only one offer.

VII.3 The costs of the offer preparation shall be incurred by the offering party.

VII.4 Offers must be submitted no later than: **16/11/2018 23:59 (CET)** and must be written on the form as in Appendix 1 to the request for proposals

VII.5 Offers shall be issued only via email to: [j.lipner@oncoarendi.com](mailto:j.lipner@oncoarendi.com)

VII.6 The date of receiving the email shall be considered as the date of issuing the offer.



- VII.7 Offers that do not meet the deadline, are incomplete or sent to the wrong email address will not be taken into consideration.
- VII.8 Any questions concerning the Object of the tender should be addressed to [j.lipner@oncoarendi.com](mailto:j.lipner@oncoarendi.com) (+48 512 974 496) no later than **14/11/2018 16:00 (CET)**. Contact person is: Joanna Lipner.
- VII.9 Any questions concerning the formal issues of the tender should be addressed to [j.lipner@oncoarendi.com](mailto:j.lipner@oncoarendi.com) (+48 512 974 496) no later than **14/11/2018 16:00 (CET)**.
- VII.10 The offer should include the validity date (at least 30 days from the submission deadline).
- VII.11 The price should be set in both Net and Gross.
- VII.12 The values in the offer (Net and Gross) should be rounded to two decimals with the mathematical rule of rounding the numbers (according to § 5 section 6 of the Regulation of the Minister of Finance of 28 November 2008 (Journal of Laws of 2008, No. 212, item 1337, as amended).
- VII.13 The offer price should include VAT. The correct determination of VAT is the responsibility of the contractor - in accordance with the provisions of the Act of 11 March 2004 on Goods and Services Tax (Journal of Laws of 2004 No. 54, item. 535 as amended).
- VII.14 The offer shall not be prepared in price variants.
- VII.15 The financial settlements between the Ordering Party and the Contractor may be made in in PLN, EUR, USD or GBP.

### VIII. TENDER RESULTS

The bidder will be informed about choosing his offer via email. Formal results will be also published on the Ordering Party's website ([www/oncoarendi.com](http://www/oncoarendi.com)) and the concurrency database.

### IX. MOST IMPORTANT PROVISIONS OF THE AGREEMENT

- IX.1. Supplier will be obligated to enter into the agreement including all conditions presented in the Request for the Offer in the place and time specified by the Ordering Party.
- IX.2. It is not possible to introduce significant changes to the content of the agreement in relation to the content of the offer, which was the base for the Service Provider selection, unless:
- a) the amendments concern performing additional services by the Service Provider, not covered by the basic contract, provided they are necessary and the following conditions are met:
    - i. the change of the Service Provider cannot be made due to economic or technical reasons, in particular concerning the interchangeability and interoperability of equipment, services or installations, ordered as part of the basic contract,
    - ii. the change of the Service Provider would cause significant inconvenience or substantial cost increase to the Ordering Party,
    - iii. the value of any subsequent changes do not exceed 50% of the basic contract value,
  - b) the amendment does not lead to a change in the nature of the contract and the following conditions are met:
    - i. the need for the contract change is brought about by circumstances which the Ordering Party, acting with due diligence, could not foresee,
    - ii. the value of a change does not exceed 50% of the basic contract value,
  - c) the amendment does not lead to a change in the nature of the contract and the total value of changes is less than 209 000 EUR, and at the same time is less than 10% of the basic value

Any contract amendment must be done in writing, otherwise will not be valid.

### X. APPENDENCIES:

- A. The offer form (Appendix No. 1).
- B. Statement concerning fulfilment of all the requirements set out in part IV of the Request for offers (Appendix No. 2).
- C. Statement concerning personal or/and capital connections between the Service Provider and the Ordering Party (Appendix No. 3).
- D. Declaration of compliance with the information obligations provided for in Article 13 or Article 14 of the GDPR (Appendix No. 4).